DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 1/16/08. Claims 1-37 are cancelled. Claims 50-73 and 76-79 are withdrawn. Claims 88-97 are newly added. Claims 38-49, 74, 75, and 80-82 have been amended. Claims 38-97 are pending. Claims 38-49, 74, 75, and 80-97 are rejected.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 38-49, 83, and 95 are rejected under 35 U.S.C. 102(e) as being anticipated by Douglas et al. (6,039,688).

(A) Referring to claim 38, Douglas discloses a method for automatically customizing medical protocols, comprising the steps of (col. 2, lines 30-47 of Douglas):

receiving data relating to one or more patients (col. 2, lines 30-41 of Douglas);

customizing one or more medical protocols including a medication regimen based on the received data to derive one or more customized medical protocols (col. 2, lines 30-47 and col. 6, lines 7-13 of Douglas);

transmitting the one or more customized medical protocols and/or information associated therewith to one or more medical monitoring devices associated with the one or more patients (Fig. 1 and col. 5, lines 27-53 of Douglas);

using the medical monitoring devices, monitoring the health status of the one or more patients (col. 6, lines 58-65 and col. 7, lines 54-65 of Douglas).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 39, Douglas discloses wherein the one or more medical protocols include a medical treatment plan (col. 2, lines 40-44 of Douglas; the Examiner interprets "therapeutic program" to be a form of "medical treatment plan").

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(C) Referring to claim 40, Douglas discloses wherein the data relating to a patient is received from a medical monitoring device associated with the patient, the data including a response to a medical questionnaire (col. 18, lines 6-17 of Douglas).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(D) Referring to claim 41, Douglas discloses wherein the information related to a customized medical protocol comprises one or more medical questionnaires (col. 18, lines 6-17 of Douglas).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(E) Referring to claim 42, Douglas discloses wherein the information related to a customized medical protocol is received from the customized medical protocol (col. 2, lines 40-66 of Douglas).

(F) Referring to claim 43, Douglas discloses wherein the information related to a customized medical protocol is received by a corresponding medical monitoring device (col. 5, lines 28-64 of Douglas).

(G) Referring to claim 44, Douglas discloses wherein the information related to a customized medical protocol is converted by a corresponding medical monitoring device that receives the information (abstract and Fig. 1 of Douglas).

(H) Referring to claim 45, Douglas discloses wherein the one or patients have at least one common characteristic (col. 7, lines 23-37 of Douglas).

(I) Referring to claim 46, Douglas discloses wherein the common characteristic relates to demographics (col. 7, lines 23-28 of Douglas; the Examiner interprets "age" to be a form of "demographic").

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(J) Referring to claim 47, Douglas discloses wherein each of the medical monitoring devices is associated with a corresponding patient and is used to

monitor the corresponding patient based on a medical protocol (col. 15, lines 51-58 of Douglas).

(K) Referring to claim 48, Douglas discloses wherein the medical monitoring device associated with a corresponding patient is configured for performing, based on a medical protocol, posing a questionnaire and gathering a response thereof (col. 18, lines 6-17 of Douglas).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(L) Referring to claim 49, Douglas discloses wherein the step of customizing comprises:

customizing a medical protocol related to a patient based on data received from a medical monitoring device associated with the patient (col. 2, lines 30-47 of Douglas);

determining one or more characteristics of the patient (col. 7, lines 24-37 of Douglas);

identifying one or more different patients who possess the one or more characteristics (col. 7, lines 24-37 of Douglas); and

customizing one or more medical protocols related to the one or more different patients (col. 7, lines 24-43 of Douglas).

(M) Referring to claims 83, Douglas discloses wherein the customized medical protocols include a medication protocol customized for each patient (col. 2, lines 40-47 and col. 7, lines 15-21 & 28-31 of Douglas).

(N) Referring to claim 95, Douglas discloses wherein the medical monitoring device transmits the monitored medical protocol information to a remote device, which analyzes the information, and transmits information to a second remote device, based upon the analysis (col. 2, lines 30-66, col. 5, lines 27-33, col. 7, lines 54-65, and abstract of Douglas).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 74-75, 80-82, 84-87, 88-91, 93-94, and 96-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (6,039,688) in view of Goodman (5,827,180).

(A) Referring to claim 74, Douglas discloses a machine-implemented method for automatically customizing medical protocols, comprising the steps of (col. 2, lines 30-47 of Douglas):

receiving medical data associated with a patient (Fig. 1, col. 2, lines 30-47, and col. 5, lines 27-33 of Douglas);

identifying one or more other patients who have characteristics common to the patient (col. 7, lines 23-37 of Douglas);

retrieving information associated with the one or more patients (col. 7, lines 23-37 of Douglas);

customizing medical protocols including medication regimens associated with the patient and the one or more other patients based on the received data and the retrieved information to derive customized medical protocols for the patient and the one or more other patients (col. 7, lines 23-44 and col. 6, lines 7-13 of Douglas);

transmitting the customized medical protocols and/or information associated therewith to medical monitoring devices associated with the patient and the one or more other patients (Fig. 1 and col. 5, lines 27-33 of Douglas).

Douglas does not expressly disclose using the medical monitoring device, monitoring compliance by the patient to the medication regimen.

Goodman discloses using the medical monitoring device, monitoring compliance by the patient to the medication regimen (col. 2, lines 36-41 and col. 4, lines 40-60 of Goodman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Goodman within Douglas. The motivation for doing so would have been to monitor the effect of the treatment (col. 2, lines 36-41 of Goodman).

(B) Referring to claim 75, Douglas discloses a system for customizing medical protocol, comprising (col. 2, lines 30-47 of Douglas):

receiving means configured for receiving data relating to one or more patients (col. 7, lines 23-37 of Douglas);

customizing means configured for automatically customizing one or more medical protocols including medical regimens based on the received data to derive one or more customized medical protocols (col. 7, lines 23-44 and col. 6, lines 7-13 of Douglas); and

transmission means configured for transmitting the one or more customized medical protocols and/or information associated therewith to one or more medical monitoring devices associated with the one or more patients (Fig. 1 and col. 5, lines 27-33 of Douglas).

Douglas does not expressly disclose monitoring means for monitoring compliance with the medication regimen by a patient.

Goodman discloses monitoring means for monitoring compliance with the medication regimen by a patient (col. 2, lines 36-41 and col. 4, lines 40-60 of Goodman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Goodman within Douglas. The motivation for doing so would have been to monitor the effect of the treatment (col. 2, lines 36-41 of Goodman).

(C) System claim 80 repeats the subject matter of claim 74 as a set of "means-plus-function" elements rather than a series of steps. As the underlying process has been shown to be fully disclosed by the teachings of Douglas and Goodman in the above rejection of claim 74, it is readily apparent that the Douglas and Goodman references include a system to perform the recited functions. As such,

these limitations are rejected for the same reasons provided in the rejection of claim 74 and incorporated herein.

(D) Referring to claim 81, Douglas discloses a method for customizing a medical protocol of a patient, comprising the step of (col. 2, lines 30-47 of Douglas):

implementing one or more medical monitoring devices to (Fig. 1 of Douglas):

provide medical questionnaires to one or more patients (col. 18, lines 6-17 of Douglas),

receive from the patient answers to one or more questions from the questionnaire (col. 18, lines 6-17 of Douglas), and

based at least in part upon the answers to the one or more of the questions by an individual patient, provide a medication regimen, and trigger an event conveying information to the individual patient (col. 7, lines 15-44, col. 6, lines 7-13 and col. 18 ,lines 38-62 of Douglas).

Douglas does not expressly disclose *selecting a specific questionnaire* to provide to the patient based on one or more shared characteristics of the patients.

However, Douglas does disclose selecting a program for the patient based on one or more shared characteristics of the patients (col. 7, lines 25-44 and Fig. 6 of Douglas). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Douglas to include a specific questionnaire with the motivation of eliciting information that would provide a more accurate analysis.

Douglas also does not expressly disclose information regarding the administration of a medication based on the medication regimen and monitoring patient compliance to the medication regimen.

Goodman discloses information regarding the administration of a medication based on the medication regimen and monitoring patient compliance to the medication regimen (col. 2, lines 36-41, col. 4, lines 40-60, and abstract of Goodman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Goodman within Douglas. The motivation for doing so would have been to monitor the effect of the treatment (col. 2, lines 36-41 of Goodman).

(E) Referring to claim 82, Douglas discloses wherein the event includes providing a recommendation to the patient to carry out one or more behaviors related to managing their health (col. 18, lines 42-54 of Douglas).

Insofar as the claim recites "one or more of," it is immaterial whether or not the other elements are also disclosed.

(F) Claims 84-87 repeat substantially the same limitations as claim 83 and are rejected for the same reasons given above.

(G) Referring to claim 88, Douglas does not disclose using the medical monitoring devices, prompting the one or more patients to take medication in accord with the medication regimens, and modifying the medical protocol based on the monitored compliance.

Goodman discloses using the medical monitoring devices, prompting the one or more patients to take medication in accord with the medication regimens, and modifying the medical protocol based on the monitored compliance (col. 4, lines 39-60 and col. 2, line 61 – col. 3, line 5 of Goodman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Goodman within Douglas. The motivation for doing so would have been to monitor the effect of the treatment (col. 2, lines 36-41 of Goodman).

(H) Referring to claim 89, Douglas does not disclose correlating monitored compliance with other of the received data for modifying the medical protocol.

Goodman discloses correlating monitored compliance with other of the received data for modifying the medical protocol (col. 2, line 61 – col. 3, line 5 of Goodman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Goodman within Douglas. The motivation for doing so would have been to ensure effective treatment (col. 2, line 36 – col. 3, line 5 of Goodman).

(I) Referring to claim 90, Douglas does not disclose generating voice prompts for prompting the one or more patients to take medication in accord with the medication regimens.

Goodman discloses generating voice prompts for prompting the one or more patients to take medication in accord with the medication regimens (col. 13, lines 18-31 and col. 7, line 66 - col. 8, line 16 of Goodman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Goodman within Douglas. The motivation for doing so would have been to provide reminders to the patients (col. 13, lines 18-31 of Goodman).

(J) Referring to claim 91, Douglas does not expressly disclose recording the medication compliance of the one or more patients.

Goodman discloses recording the medication compliance of the one or more patients (col. 4, lines 40-60 of Goodman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Goodman within Douglas. The motivation for doing so would have been to have the data needed to provide alerts to the patients (col. 4, lines 40-60 of Goodman).

(K) Referring to claim 93, Douglas does not disclose wherein the means for customizing is responsive, in part, to monitored medication regimen compliance.

Goodman discloses wherein the means for customizing is responsive, in part, to monitored medication regimen compliance (abstract and col. 8, lines 56-63 of Goodman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Goodman within Douglas. The motivation for doing so would have been to ensure effective treatment (col. 2, line 36 – col. 3, line 5 of Goodman).

(L) Referring to claim 94, Douglas does not disclose wherein the device is further implemented to provide voice prompts.

Goodman discloses wherein the device is further implemented to provide voice prompts (col. 8, lines 6-16 of Goodman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Goodman within Douglas. The motivation for doing so would have been to provide reminders to the patients (col. 13, lines 18-31 of Goodman).

(M) Referring to claim 96, Douglas does not disclose wherein information related to compliance to the medication regimens is transmitted from one or more medication containers or packages remotely located from the medical monitoring device.

Goodman discloses wherein information related to compliance to the medication regimens is transmitted from one or more medication containers or packages remotely located from the medical monitoring device (col. 11, line 43 – col. 12, line 24 of Goodman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Goodman within Douglas. The motivation for doing so would have been to track information regarding the dispensing of medication (col. 11, line 43 – col. 12, line 24 of Goodman).

(N) Referring to claim 97, Douglas does not disclose wherein the transmission of information is via wireless communication.

Goodman discloses wherein the transmission of information is via wireless communication (col. 5, line 64 - col. 6, line 1 of Goodman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Goodman within Douglas. The motivation for doing so would have been to have messaging capabilities (col. 5, line 64 – col. 6, line 1 of Goodman).

6. Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (6,039,688) in view of Brown (US 2003/0229514 A2).
(A) Referring to claim 92, Douglas does not disclose generating voice prompts for querying one or more patients regarding their health status, and prompting the one or more patients to provide answers to one or more queries related to their health status.

Brown discloses generating voice prompts for querying one or more patients regarding their health status, and prompting the one or more patients to provide answers to one or more queries related to their health status (para. 3 and para. 5, page 4 of Brown).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Brown within Douglas. The motivation for doing so would have been to monitor patients remotely to avert medical problems before they become complicated and costly (para. 2, lines 8-11 of Brown).

Response to Arguments

7. Applicant's arguments with respect to claims 74-75, 80-81, 88, 90, and 92-94 have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's additional arguments filed 1/16/08 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 1/16/08.

(1) Applicant argues that Douglas does not monitor medication regimen compliance using medical monitoring devices per independent claim 38.

(A) In response to the first argument, the Examiner respectfully submits that Douglas discloses medication regimens (see col. 6, lines 7-13 of Douglas). Furthermore, insofar as the claim recites "at least one of," it is immaterial whether or not Douglas discloses monitoring medication regimen compliance using medical monitoring devices.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. N./
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